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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/668,484  | 09/22/2003  | Venkatram P. Shastri | T1118/2007I         | 2930             |
| 3000  | 7590        | 10/03/2006           | EXAMINER            |                  |
| CAESAR, RIVISE, BERNSTEIN,<br>COHEN & POKOTILOW, LTD.<br>11TH FLOOR, SEVEN PENN CENTER<br>1635 MARKET STREET<br>PHILADELPHIA, PA 19103-2212 |             |                      | KENNEDY, SHARON E   |                  |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             | 1615                 |                     |                  |
| DATE MAILED: 10/03/2006   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/668,484             | SHASTRI ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Sharon E. Kennedy      | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 July 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 8-13, 21, 23, 24, 27-30 and 32-52 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7, 14-20, 22, 25, 26, 31, 53, 54 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Election/Restrictions***

Applicant argues that claims 13 and 27 were improperly withdrawn from consideration. However, applicant elected the metal as a surface. Nothing in claim 3 is directed to a metal. Claim 27 recites a structure of silica, which is a ceramic. Note that claim 8 is withdrawn as reciting a group of ceramics. This group includes silica. Silica is a ceramic structure as recited in the claims. It is unclear what applicant implies by defining the silica as "(oxide) silica".

Claims 8-13, 21, 23, 24, 27-30, 32-52 remain withdrawn from consideration.

### ***Claim Rejections - 35 USC § 102***

Claims 1-5, 6, 14, 25, 53, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Greco et al., US 4,740,382. Regarding claim 1, Greco discloses the orthopedic implant (column 1, lines 57-63) which constitutes the device, the Sepharose-CM particles which constitutes the functional layer, the antibiotic bonded ionically to the Sepharose constitute the claimed functional group modifying a property of the device. Note that the particles have a diameter of between 5 to 40 microns. The particles are absorbed into the grafts.

Claims 1, 2, 4, 5, 14, 20, 25, 26, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Cote et al., US 6,485,703. Cote discloses polyethylene glycol coatings comprising hydrogel particles to improve the biocompatibility of glucose sensors. See especially column 9, lies 40+. Note that the particles are considered to be "adhered" to the substrate (column 5, line 61). Note the particle sizes in column 13, particularly line 20. See also line 38 (10 microns disclosed). The particles are modified with a functional group to detect glucose, and are to be coated on sensors such as semiconductors for this purpose. Regarding the claimed semiconductor implant, see the discussions related to the formation of sensors and especially column 46, lines 59+, especially line 63, which explicitly discloses the semiconductor.

Claims 1, 2, 3, 4, 5, 6, 14, 20, 22, 25, 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Santos et al., US 5,955,096. Santos discloses particulates having a diameter of less than about 2 microns (claims 15-17), which are modified by the addition of an anhydride oligomer to enhance its adhesiveness. Santos' claim 28 states that the particles may be coated onto a drug delivery device. Regarding claims 20 and 22, note that metal oxides may be combined with the particles to improve bioadhesion. See column 3, line 33. Regarding claim 26, Santos discloses the anhydride group, which is akin to a carboxy group.

#### ***Claim Rejections - 35 USC § 103***

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote '703. Applicant claims the specific polydispersity and shape. It is agreed by those

skilled in the art that having a lower polydispersity and substantially spherical particles is superior but it tempered by the cost in producing these more accurately formed particles. Further, applicant's ranges are typical for the art and further applicant does not recite any unexpected benefit from recited dimensions. Accordingly, it would be obvious to one of ordinary skill in the art to make the Cote invention with the particular polydispersity and shape if such were necessary to ensure proper functioning of the sensor layer.

Claims 7, 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco '382. Regarding claim 7, Greco does not explicitly disclose metal surfaces, however, it is well known that heart valves, profusion pumps and orthopedic implants are made of metal, especially stainless steel. Accordingly, the examiner takes the position that it would be obvious to one of ordinary skill in the art to apply the Greco coating to any implantable device as outlined in the specification.

Claims 1, 2, 4, 5, 6, 7, 14, 20, 25, 31, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spector et al., US 4,362,681. Spector discloses a metal hip replacement device having a surface (metal) modified with a polymeric particulate such as sintered polysulfone. The polymeric particulate anticipates applicant's claimed functional layer. The functional group is the oxidized sulfur group. This functional group modifies a property of the device, the property being enhancing tissue ingrowth in view that the polysulfone has a high affinity for water and is wettable (claim 31). Regarding claim 7, see column 13, lines 1-4. These metals represent the modified surface.

Accordingly, the only difference between the Spector device and applicant's claimed invention is the particle size. Spector discloses a particle size of from about 300 microns to about 50 microns. However, it would be obvious to one of ordinary skill in the art to modify the particle size if the pore sizes were smaller. This would have the effect of lowering the ingrowth of material into the prosthetic, useful if the prosthetic were temporary.

***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

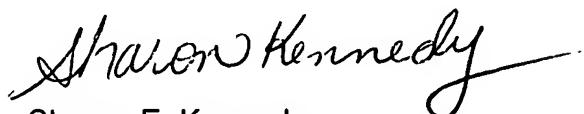
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615